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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,159	07/09/2003	Elizabeth Charuvastra		2722

44124 7590 12/20/2005

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,159	CHARUVASTRA ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The amendments to the specification are acknowledged and accepted.

Claim Objections

2. The amendment to claim 12, correcting the dependence on claim 7 is acknowledged and accepted.

Response to Arguments

3. Applicant's arguments filed 12/5/2005 have been fully considered but they are not persuasive. With respect to claims 13 and 14, Applicant argued that Callahan (US 6,324,423) does not disclose comparing a subject's histogram before and after administration of a drug. However, this is clearly stated in column 7, line 14. Applicant also argued that Callahan does not disclose comparing the histogram of a subject receiving a drug to a composite histogram of a population not receiving the drug. This argument is persuasive; but moot, in light of the new grounds for rejection, necessitated by amendment.

4. In response to the other arguments concerning claims 13 and 14, Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

5. In respect to claims 1-12 and 15-19, Applicant argued that the Glass (US 2005/0165320) reference does not anticipate independent claims 1, 7, and 15 because Glass uses blocks of 100 R-R intervals instead of beat-to-beat data, as claimed. Applicant further argued that, because the independent claims are not anticipated, the rejections of the dependent claims are moot. However, in its broadest reasonable interpretation, the R-R interval is the time period between successive heartbeats, or beat-to-beat data, thus anticipating the independent claims 1, 7, and 15. Additionally, Glass discloses that any number (including one) of R-R intervals can be used (par. 0048).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 3, 6, 14, 15, 16, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Glass et al. (2005/0165320). Glass et al. disclose a method for detecting cardiac arrhythmia based on comparing a subject's histogram with composite

histograms of R-R intervals after exposure to a drug (par. 0012). In regards to claims 16 and 18, the individual histogram is compared to a set of subjects who are "normal" for a given R-R interval to determine if the individual is from the group used to construct the composite curve. In regards to claim 19, the composite curves are derived from subjects with baseline characteristics and the individual histogram is derived from a potentially normal subject.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Callahan et al. (6,324,423 B1). Callahan discloses a method involving providing a drug to a

subject (col. 4, line 6), collecting beat-to-beat data representing a cardiac interval (col. 3, line 67), defining bins with value ranges (col. 4, line 1), organizing data into bins to create a composite histogram and comparing the data with a baseline measurement (col. 7, line 14), but does not expressly disclose comparing the dosed condition with a histogram corresponding to a group of subjects not provided the drug. It is well known in the art that when determining whether the sample comes from the population, a larger population size should be used to more likely reflect the "normal" value (Central Tendency Theorem). Alternatively, Callahan discloses comparing samples for individual patients to "normal clinical limits", which inherently result from sampling a population of patients, to see how the sample condition compares to the normal condition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made modify Callahan's invention by comparing the histogram of a dosed patient to the histogram of a group of un-dosed patients to accurately determine the effect of the dosing condition.

11. Claims 7, 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass et al. Glass et al. substantially disclose the claimed invention except for comparing a histogram from one group of subjects to another histogram from another group of subjects. It is well-known in the art to compare characteristics, such as means, standard deviations, and histograms of two groups to determine if they are from the same population. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use two composite histograms to determine if two groups are from the same population.

12. Claims 4, 5, 10, 11, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass et al. in view of Callahan et al. Glass et al. disclose the essential features of the claimed invention except for an interval measurement comprising an amplitude measurement, obtaining an ambulatory ECG recording, and comparing an individual histogram to a placebo histogram. Callahan et al. teach of measuring an amplitude to create histograms based on variables other than time (claim 4), using an ambulatory ECG recording device to allow long-term ECG recording outside of a clinical environment (claim 5), and comparing an individual histogram to a placebo histogram to determine the probability that the two groups are the same (col. 9, line 17). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to measure an amplitude to create histograms based on variables other than time, use an ambulatory ECG recording device to allow long-term ECG recording outside of a clinical environment, and compare an individual histogram to a placebo histogram to determine the probability that the two groups are the same.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE R. EVANISKO
PRIMARY EXAMINER

12/15/

MWK